

Claims

1. A composition comprising nimesulide in a glyceryl monoolein-solvent phase comprising glyceryl monoolein in an amount of 17-59% by weight of the composition.

2. A composition comprising nimesulide in a glyceryl monoolein-solvent phase, wherein the glyceryl monoolein-solvent phase has a liquid crystal structure.

3. A composition comprising nimesulide in an amount of 0.1-5% by weight of the composition, glyceryl monooleate in an amount of 17-59% by weight of the composition and a non-aqueous solvent in an amount of 40-82% by weight of the composition.

4. A composition according to claim 3, wherein the nimesulide is used in an amount of 0.1-3% by weight, preferably in an amount of about 1% by weight of the composition.

5. A composition according to claim 3 or 4, wherein the non-aqueous solvent is a solvent system containing DGME in an amount of 35-45% by weight and ethanol in an amount of 25-35% by weight of the composition.

6. A composition according to any of claims 3 or 4, wherein the non-aqueous solvent is DGME used in an amount of 40-82% by weight, preferably in an amount of 60-82% by weight of the composition.

7. A composition according to ^{IMD} ~~any of claims 3 to 6~~ ^{claim 3}, which further comprises a gelling agent in an amount of 0.5-3% by weight of the composition.

8. A composition according to claim 7, wherein the gelling agent is hydroxypropylcellulose.

9. A composition according to ^{claim 3} ~~any of claims 3 to 8~~, which further comprises water in an amount of 0-15% by weight of the composition.

10. A composition according to claim 9, wherein water is used in an amount of 0-10% by weight of the composition.

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a (11) A composition according to claim 9 ~~or 10~~, wherein the composition does not
5 contain any water.

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a (12) A composition according to *claim 3* ~~any of claims 3 to 11~~, which further comprises at least
one other additive in an amount of up to 0.25% by weight, preferably 0.001-0.25% by
weight of the composition.

10 13. A composition according to claim 12, wherein the at least one other additive is
selected from the group consisting of capsicum oleoresin, capsaicin, nicotinate, camphor,
menthol, turpentine oil, preservatives such as propylparaben, antioxidants such as BHT or
BHA, sequestrant agents such as EDTA or colorants such as FD&C Blue 1 or Yellow #5.

15 a (14) A composition according to *claim 1* ~~any preceding claims~~, wherein the composition is in
the form of a gel, solution, ointment or spray; preferably a gel.

20 a (15) A process for the preparation of a composition according to *claim 1* ~~any preceding claims~~,
which comprises the following steps:

(i) dissolving nimesulide in non-aqueous solvent(s) to form a solution, which is
heated to 30-90°C;

(ii) mixing this solution with glyceryl monoolein, which has previously been heated
to 35-55°C;

25 (iii) followed by agitation and cooling to room temperature to form a clear
nimesulide solution.

a (16) A process for the preparation of a composition according to *claim 1* ~~any preceding claims~~,
which comprises the following steps:

30 (i) dissolving glyceryl monoolein in non-aqueous solvent(s) to form a solution,
which is heated to 30-90°C;

(ii) mixing this solution with nimesulide;

(iii) followed by agitation and cooling to room temperature to form a clear nimesulide solution.

a 17. The process of claim 15 ~~or 16~~, further comprising the step of:

5 (iv) mixing a gelling agent into the nimesulide solution, either on its own or as a gel prepared with the non-aqueous solvent(s). B

a (18.) ^{IMO} The process of ^{claim 15} ~~any of claims 15 to 17~~, further comprising the step of:

(v) mixing water into the solution or gel.